



Attorney's Docket No.: 07333-04300

26/11

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Hartounian et al.

Art Unit : 1641

Serial No. : 09/192,064

Examiner : Gollamudi Kishore, Ph.D.

Filed : September 10, 2001

Title : PRODUCTION OF MULTIVESICULAR LIPOSOMES

Commissioner for Patents
Washington, D.C. 20231

RESPONSE

In the Specification:

Please replace the paragraph beginning at page 17, line 25 with the following paragraph:

201
-- Sterile filtration of all fluids which enter the MVL production process is essential for an aseptic process, as envisioned in one embodiment of the present invention. Rating of pore sizes of filter membranes is by a nominal rating reflecting the capacity of the membrane to retain microorganisms of size represented by specified strains, not by determination of an average pore size and statement of distribution of sizes. Sterilizing filter membranes are those capable of retaining 100% of a culture of 10^7 organisms of a strain of *Pseudomonas diminuta* (ATTC 19146) per square cm of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally rated 0.22 μm or 0.2 μm , depending on the manufacturer. Bacterial filter membranes capable of retaining only larger microorganisms (including *Serratia marcescens* (ATTC 14756)) are labeled with a nominal rating of 0.45 μm . Filter membranes used in the present processes are of the 0.2 μm type, and are used in all lines feeding from liquid solution and gas storage tanks to vessels and transfer lines used to manufacture product.--

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit

September 30, 2003

Signature

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